

**2009 H1N1 Influenza
Updated Key Points
November 6, 2009**

What's New and Updated

- Activity Update
- International Situation Update
- 2009 H1N1 Influenza Vaccine
- 2009 H1N1 Influenza Vaccine Safety
- Seasonal Influenza Vaccine

A Summary of CDC Key Public Health Messages this Season

- Flu activity remains high in the United States. Forty-eight states are reporting widespread flu activity. Nationally, visits to doctors for influenza-like-illness declined slightly from last week, but are still very high. Flu-related hospitalizations and deaths continue to increase and are very high nation-wide compared to what is expected for this time of year
- While influenza is unpredictable, high levels of influenza activity may continue for several weeks, and even after flu activity peaks, it's possible that other waves of influenza activity may occur – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- CDC recommends a three-step approach to fighting the flu:
 - vaccination;
 - everyday preventive actions, including covering coughs and sneezes, frequent hand washing, and staying home when sick;
 - and the correct use of antiviral drugs if your doctor recommends them.
- 2009 H1N1 vaccination has begun. Supplies are increasing daily, but remain limited. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine becomes available. There will be enough vaccine available for anyone who wishes to receive it.

Activity Update

- It's very important that antiviral drugs be used early to treat flu in people who are very sick (for example people who are in the hospital) and people who are sick with flu and have a greater chance of getting serious flu complications, like people with asthma, diabetes or people who are pregnant.
- Each week CDC analyzes information about influenza disease activity in the United States and publishes findings of key flu indicators in a report called [FluView](#).

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- Information collected during the week of October 25-31, 2009 is reported in FluView on November 6, 2009.
- Below is a summary of the most recent key indicators:
- Visits to doctors for influenza-like illness (ILI) nationally decreased very slightly this week over last week after four consecutive weeks of sharp increases.
- While ILI declined slightly, visits to doctors for influenza-like illness remain at much higher levels than what is expected for this time of the year and parts of the country continue to see sharp increases in activity.
- It's possible that nationwide ILI could rise again. ILI continues to be higher than what is seen during the peak of most regular flu seasons.
- Total influenza hospitalization rates for laboratory-confirmed flu continue to climb and are higher than expected for this time of year.
- Hospitalization rates continue to be highest in younger populations with the highest hospitalization rate reported in children 0-4 years old.
- The proportion of deaths attributed to pneumonia and influenza (P&I) based on the 122 Cities Report continues to increase and has been higher for five weeks now than what is expected at this time of year.
- In addition, 18 flu-related pediatric deaths were reported this week; 15 of these deaths were confirmed 2009 H1N1, and three were influenza A viruses, but were not subtyped.
- Since April 2009, CDC has received reports of 129 laboratory-confirmed pediatric 2009 H1N1 deaths and another 15 pediatric deaths that were laboratory confirmed as influenza, but where the flu virus subtype was not determined. (More information on these pediatric deaths is available below.)
- Forty-eight states are reporting widespread influenza activity at this time; a decline of one state over last week. They are: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.
- This many reports of widespread activity at this time of year are unprecedented during seasonal flu.

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- Almost all of the influenza viruses identified so far continue to be 2009 H1N1 influenza A viruses.
- These viruses remain similar to the virus chosen for the 2009 H1N1 vaccine, and remain susceptible to the antiviral drugs oseltamivir and zanamivir with rare exception

Pediatric Deaths

- During Week 43 (the week ending October 31, 2009), 18 influenza-associated pediatric deaths were reported to CDC.
 - These deaths occurred in California [8], Indiana, Louisiana [2], Mississippi, New York, Oklahoma, Texas [2], Virginia, and West Virginia.
 - Fifteen of these deaths were confirmed 2009 H1N1, and three were influenza A viruses, but untyped.
 - These deaths occurred between July 12 and October 31, 2009.
 - Seven deaths reported this week, occurred during the 2008-09 flu season, bringing the total number of reported pediatric deaths that occurred during that season to 124.
- The cumulative total number of laboratory-confirmed pediatric deaths related to 2009 H1N1 since April 2009 is 129. (Since August 30, 2009 when the flu season "re-set", CDC has received reports of 85 flu-associated pediatric deaths; 73 of these were due to 2009 H1N1, and the remaining 12 were influenza A viruses that were not subtyped.)
- A table showing reports of flu-related pediatric deaths (including a cumulative total of 2009 H1N1 pediatric deaths since April, 2009) is available on the CDC website at <http://www.cdc.gov/h1n1flu/updates/us/#pedh1n1cases> .
- Since CDC began tracking pediatric flu-related deaths in 2003-2004, the number of pediatric deaths reported to CDC has ranged from 46 during the 2005-2006 season to 153 during the 2003-2004 season.
- Information on how hospitalizations and deaths are being reported this season is available at <http://www.cdc.gov/h1n1flu/reportingqa.htm>

International Situation Update

- The 2009 H1N1 influenza virus is the predominant influenza virus in circulation in most countries worldwide.
- In temperate regions of the Southern Hemisphere, little disease due to 2009 H1N1 has been reported.

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- The epidemiology of disease caused by 2009 H1N1 influenza in the Southern Hemisphere has been very similar to what was described in the United States in the spring of 2009.
- There have been no significant changes detected in the 2009 H1N1 influenza viruses isolated from persons in the Southern Hemisphere as compared to viruses isolated from persons in the Northern Hemisphere.
- In tropical regions of the Americas and Asia, influenza activity due to 2009 H1N1 remains variable.
- In temperate regions of the Northern Hemisphere, high rates of influenza-like illness (ILI) activity due to 2009 H1N1 continues to increase across many countries in Europe and Asia, as well as parts of the United States, Mexico and Canada.
- According to the World Health Organization (WHO), the majority of 2009 H1N1 influenza isolates tested worldwide remain sensitive to oseltamivir, an antiviral medicine used to treat influenza. Worldwide, only 42 2009 H1N1 isolates tested have been found to be resistant to oseltamivir – 14 of these isolates were detected in the United States.
- The World Health Organization (WHO) continues to report updated 2009 H1N1 flu-associated laboratory-confirmed cases and deaths on its Web page (<http://www.who.int/csr/disease/swineflu/updates/en/>). These laboratory-confirmed cases represent a substantial underestimation of total cases in the world, as many countries focus surveillance and laboratory testing only on people with severe illness.
- Since April 19, 2009, more than 60 percent of all influenza specimens reported to WHO have been 2009 H1N1.
- On September 17, 2009, several countries including the United States announced plans to donate 2009 H1N1 vaccine or funds to support vaccination campaigns in less developed countries.

2009 H1N1 Influenza Vaccine

In this Section:

- Supply
- Recommendations
- Research

Supply

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- The aggregate number of 2009 H1N1 flu vaccine doses allocated are now being posted daily by 12:00 PM ET and are available at <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>.
- **(Updated)** As of Wednesday, November 4, 2009, there were a total of 28,036,300 doses ordered and a total of 26,248,100 shipped.
- **(Updated)** As of Friday, November 6, 2009, a total of 38,038,100 doses were available for ordering. Of those available doses, 27,480,000 doses were injectable (flu shots) and 10,558,100 were LAIV (nasal spray vaccine).
- The vaccine situation changes rapidly – throughout each day, vaccine is being shipped from the vaccine manufacturers to McKesson distribution centers; orders are coming into McKesson; orders are being processed and shipped; and vaccine is arriving in thousands of places across the country.
- 2009 H1N1 vaccination has begun but initial supplies are small. More doses are expected for shipment each week. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine becomes available. There will be enough vaccine available for anyone who wishes to receive it.
- First doses of 2009 H1N1 vaccine were administered outside of the clinical trials on Monday, October 5, 2009.
- Initial doses of 2009 H1N1 “flu shot” were shipped the week of October 12, with additional doses scheduled for shipment each week.
- The challenges associated with the U.S. influenza vaccine supply are multi-faceted. Influenza viruses change from year to year, so influenza vaccines must be updated annually to include the viruses that research indicates are most likely to circulate in the upcoming season. Once the viruses are selected for the new formulation, manufacturers operate under a very tight timeline for producing, testing, releasing and distributing the vaccine. Due to these time constraints, any problems encountered during production may cause shortages or delays, and in fact, such problems have impacted the seasonal supply during some recent influenza seasons, and can occur with any type of influenza vaccine, including the 2009 H1N1 vaccine.
- The vaccine development process is complex and forecasting how much vaccine will be available at a certain time is challenging and amounts will vary from week to week. Millions of doses of vaccine are in the pipeline and federal, state and local public health authorities are working hard to get vaccine out to the public as soon as it is received.

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- A decision had to be made between waiting to distribute vaccine until large quantities were ready to be shipped versus distributing limited quantities of the vaccine sooner. The latter was chosen knowing that it would create some challenges and frustrations (for our public health partners in the states, providers, and the public), but also knowing that it would allow for people to start being protected against this disease sooner.
- It also is important to keep in mind that there will be lag times between states placing orders and vaccine actually being distributed (we are not cutting corners in terms of steps like quality control checks) - and any number of things can create lag times between time of distribution to states and when vaccine actually arrives in provider offices or clinics.
- This vaccine program is a massive and challenging undertaking and is being carried out at a time when state and local health departments have experienced severe budget cuts.
- **(New)** A new video podcast is now available on the CDC website; "H1N1 Flu Vaccine- Why the Delay?" explains how flu vaccines are made, manufactured, shipped and how people can find vaccine in their area. To watch the podcast, visit <http://www2c.cdc.gov/podcasts/player.asp?f=262894#> or <http://www.cdc.gov/Features/H1N1VaccineDelay/> on YouTube.
- **(New)** The federal government allocates vaccine on a pro rata basis to state health departments and some big city health departments who then make decisions about how to distribute vaccine equitably and efficiently within their jurisdictions.
- **(New)** Employee or workplace health clinics (among other locations) are a legitimate—and very effective—place to administer vaccine during a time of shortage. These clinics can and do reach and target people in priority vaccination groups, including pregnant women and 18 to 64 year workers with medical conditions that put them at higher risk for influenza complications.

Recommendations

- A report in the August 21, 2009, *Morbidity and Mortality Weekly Report* (MMWR) provides official recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against 2009 H1N1 influenza. This report is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>

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- The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible with an emphasis on vaccinating certain target groups with initial doses of vaccine.
- These recommendations:
 - 1) Identify five initial target groups for vaccination efforts comprising an estimated 159 million persons (pregnant women, persons who live with or provide care for infants younger than 6 months, health care and emergency medical services personnel, children and young adults aged 6 months through 24 years, and persons aged 25 through 64 years who have medical conditions that put them at higher risk for influenza-related complications),
 - 2) Establish a priority subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and
 - 3) Provide guidance on use of 2009 H1N1 vaccine in other adult population groups as vaccine availability increases.
- The recommendations are broad and allow for flexibility to accommodate local variability in vaccine needs and demands. Providers should be aware of and follow any additional guidance provided by their state or local health departments. If no additional guidance is provided at the state or local level, providers should vaccinate among the initial target group populations on a first come, first serve basis.
- Simultaneous administration of inactivated vaccines (shots) against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used (for example, one vaccine in each arm).
- **(New)** CDC has no recommendation regarding the administration of acetaminophen or other antipyretic drugs following influenza vaccination. You should follow the guidance of your physician or other health care provider.

Research on Public Knowledge, Attitudes and Beliefs

- **(New)** A national poll with a representative sample of 1,073 adults aged 18 and over was conducted by the Harvard School of Public Health (HSPH) on October 30 through November 1, 2009. The poll asked about people's perceptions and experiences of trying to get the H1N1 vaccine for themselves or their children.
- **(New)** 91% of the polling sample who were unable to get the 2009 H1N1 flu vaccine said that they will try again this year to get the vaccine for themselves, their children or both.
 - Even though there was only a limited amount of 2009 H1N1 vaccine available in early October, more vaccine will continue to become

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available over the upcoming weeks and months. Therefore, individuals who were unable to initially get the vaccine and plan to try again once more vaccine is available should contact various settings such as local health departments, healthcare provider websites and hotlines, schools, and other private settings, such as pharmacies and workplaces to see if the vaccine is available.

- **(New)** To view a full report of the Harvard Poll press release, visit <http://www.hsph.harvard.edu/news/press-releases/>

2009 H1N1 Influenza Vaccine Safety

In this section:

- General H1N1 Vaccine Safety
- Vaccine Safety Monitoring
- Background Rates of Medical Events

General H1N1 Vaccine Safety

- CDC expects that the 2009 H1N1 influenza vaccines will have similar safety profiles as seasonal influenza vaccines, which have very good safety track records.
- The types and frequencies of side effects from the 2009 H1N1 influenza vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.
- The most common side effects of the vaccines are pain, redness, or swelling where the shot was given in the arm or a runny nose and headache after the nasal spray.

Vaccine Safety Monitoring

- HHS released a report on the Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program: http://flu.gov/professional/federal/monitor_immunization_safety.html
- CDC and its partners are using several systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that are in use are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.
- CDC has enhanced vaccine safety monitoring efforts in several ways:
 - The Vaccine Adverse Event Reporting System (VAERS) is a voluntary reporting system that identifies potential vaccine safety signals: healthcare providers are actively reminded to report suspected issues,

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- and medical personnel are conducting daily reviews and follow-up [<http://vaers.hhs.gov>].
- Second, a new Web-based active surveillance system is being implemented to prospectively follow tens of thousands of vaccinated people [www.myflushot.org].
 - Third, large population-based systems that link computerized vaccination data with healthcare codes will be used to conduct rapid and ongoing analyses. This approach includes data from large managed care plans, other health plans, Department of Defense, Medicare and the Veterans' Administration.
 - Fourth, active case finding for GBS is being conducted in 10 areas of the United States (a combined population of about 50 million people).
 - Findings from all sources are cross-referenced and reviewed by government and outside scientists to be sure any concerns are rapidly addressed.
 - Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers.
 - An adverse event following immunization is a medical incident that occurs after someone receives an immunization.
 - Adverse events may be coincidental (meaning occurring around the same time but not related to vaccination) or caused by vaccination.
 - Adverse events can be reported by providers, manufacturers, people who were vaccinated or their caregivers.
 - The purpose of vaccine safety monitoring is timely identification of any clinically significant adverse events following immunization, as well as to provide timely information to the public, vaccine providers, public health officials, and policy makers.

Background Rates of Medical Events

- Adverse events—such as sudden deaths, spontaneous abortions, and Guillain-Barré syndrome—will occur in the population. These will occur whether or not people have been vaccinated. In the context of vaccine safety monitoring, we call these naturally occurring events “background rates.”
- Awareness of the background rates of several adverse events is critical to assessing the safety of the vaccine. This information allows public health and medical experts to identify when adverse events are occurring more frequently than would be expected in the absence of vaccination and need

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more detailed investigation to determine if the vaccine is causing the adverse events.

- Background rates are helpful as a tool to assess vaccine safety by comparing the expected rate of adverse events to the actual/observed rate in any given timeframe once vaccination begins.
- Some clustering – a number of cases in a limited timeframe or area – of adverse events occurs normally, and we can expect this clustering to continue during the period that 2009 H1N1 vaccinations are given.
- By comparing the expected rate of adverse events to the actual/observed rate in any given timeframe, we can put adverse event reports in proper context.
- There are some limitations of background rates. Background rates can vary widely by location, age, sex and ethnicity, and therefore these factors should be considered when using background rates to compare events that occur following vaccination.
- Background rates by themselves usually are not sufficient as a way to fully assess vaccine safety. Full analysis requires review of individual reports and carefully controlled epidemiologic study.
- While background rates tell us that we cannot jump to conclusions or assume that any vaccine caused a particular health event, CDC takes every single adverse event report seriously and individually reviews all reports of serious adverse events so that potential problems can be quickly detected and investigated.

Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that many more individuals have been vaccinated this season than at the same time last year. This is most likely due to the early availability of vaccine and public interest in getting vaccinated.
- CDC continues to recommend seasonal flu vaccination. Currently the vast majority of influenza being reported to CDC is 2009 H1N1. Influenza is very unpredictable but CDC expects both 2009 H1N1 flu and seasonal flu to cause illness, hospital stays and deaths this season.

Seasonal Influenza Vaccine Supply and Distribution

- Local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (<http://www.preventinfluenza.org/ivats/>) over the coming weeks.

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- The largest supplier of seasonal flu vaccine, Sanofi Pasteur is experiencing a delay in their shipments. Currently, the company has shipped more than half of the 50.5 million doses of Sanofi Pasteur seasonal flu vaccine ordered by U.S. health care providers. It could be November before customers receive their complete orders.
- CDC is working with manufacturers, states, and immunization providers to identify existing seasonal flu vaccine and get it to providers who can administer it to people who need and want it.
- Most will be able to obtain vaccine from their usual provider, but some will have to obtain the vaccine from an alternative provider
- **(Updated)** As of October 30, more than 91 million doses of seasonal influenza vaccine have been distributed (this is about 79% of doses expected this season).
- At the current time, five influenza vaccine manufacturers are projecting as many as 114 million doses of seasonal influenza vaccine will be available from currently licensed manufacturers in the United States for use during the 2009-10 influenza season.
- Manufacturer projections indicate that the vast majority of vaccine will be distributed by the end of October. However, some vaccine distribution may continue into November, including doses that are ordered during the fall.
- CDC's seasonal influenza web site is at <http://www.cdc.gov/flu> with a new design, the latest information updates, and free resources.
- (New) More information about seasonal flu vaccine supply can be found at: <http://www.cdc.gov/flu/professionals/vaccination/#supply>

Flu Activity May Occur in "Waves"

- The timing, spread and severity of influenza viruses is uncertain.
- Outbreaks of influenza may occur in different places at different times.
- Outbreaks may occur in waves of about 6-12 week time periods.
- These waves of influenza may occur over a year or so after the emergence of a new influenza virus.
- In past pandemics, "waves" of activity have been observed.
- The first wave is usually a smaller wave; followed by a larger "peak" wave. Subsequent smaller waves can occur as well.

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- The United States experienced its first wave of 2009 H1N1 pandemic activity in the spring of 2009.
- At this time, we are experiencing a second wave of 2009 H1N1 activity.
- Flu activity is widespread in most of the country at this time, which is highly unusual during regular seasonal flu for this time of year, but not unexpected for a pandemic.
- Nationally, activity is continuing to increase.
- It's not possible to predict how long activity will remain high, when this wave will peak and when activity will begin to decline.
- Even after flu activity peaks during the current wave, it's possible that other waves of influenza activity may occur – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- Because the timing and spread of influenza viruses are unpredictable, CDC is continuing to recommend vaccination with seasonal influenza vaccine and 2009 H1N1 vaccine for those people in whom it is recommended.